



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 27, 2016

MEMORANDUM

Subject: Efficacy Review for EPA File Symbol 4091-EN, Phoenix 2;
DP Barcode: 433900
E-Sub #: 11265

From: Marcus Rindal, Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Efficacy Evaluation Team
Product Science Branch
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To: Eric Miederhoff PM 31/Cletis Mixon
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: W.M. Barr & Company, Inc.
6750 Lenox Center Court, Suite 200
Memphis, TN 38115

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Alkyl* dimethyl benzyl ammonium chloride (*50%C ₁₄ , 40%C ₁₂ , 10%C ₁₆)	0.08
Didecyl dimethyl ammonium chloride	0.03
Octyl decyl dimethyl ammonium chloride	0.06
Diocetyl dimethyl ammonium chloride	0.03
<u>Other Ingredients</u>	<u>99.80</u>
Total	100.00

I BACKGROUND

The new/unregistered product, Phoenix 2 (EPA File Symbol 4091-EN), is a ready-to-use aerosol spray for use as a hard surface disinfectant with virucidal and fungicidal activity intended for use in indoor residential environments. Relevant efficacy studies were submitted to allow the product label to claim hard, nonporous surface disinfection (including supplemental bacterial, fungal, and viral claims), hard, nonporous surface sanitization, residual (24 hour) sanitization (using EPA protocol 01-1A), soft surface (fabric) sanitization, and mildewstatic properties for nonporous and fabric surfaces. The lots used in efficacy testing were formulated with the active ingredient at or below the lower certified limit. The chemical characterization reports for the lots used in each test are included in each efficacy report.

This data package contained a letter from the applicant's representative to EPA (dated April 27, 2016), EPA Form 8570-35 (Data Matrix), twenty-one studies (MRID 498987-13 through 498987-33), Statements of No Data Confidentiality Claims for all studies, and the proposed label.

II USE DIRECTIONS

The proposed label (identified as Version 060616) provides the following use directions.

{Sanitizing Directions}

Hold container 6"-8" from surface and spray until thoroughly wet.

To Sanitize Hard Non-porous surfaces: Let stand 10 seconds. Wipe clean with a [damp] cloth [or sponge] [or paper towel]. Pre-clean heavily soiled surfaces. [Kills [effective against] [99.9% of] *{Insert non-food contact sanitization bacteria from Table B}.*]

To Sanitize Hard Non-porous Surfaces FOR 24 HOURS: – Let stand 5 minutes. Allow to air dry. Pre-clean heavily soiled surfaces. [Kills [effective against] [99.9% of] *{Insert residual sanitization bacteria from Table B}*] [for 24 hours].]

To [spot] Sanitize Soft [Fabric] surfaces: Let stand for 60 seconds [-or- 1 minute]. Let air dry. [For difficult odors, repeat application] [Kills [effective against] [99.9% of] *{Insert soft surface sanitization bacteria from Table B}.*]

{Disinfecting Directions}

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

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TO DISINFECT: Hard, non-porous surfaces: Preclean surface. Hold container 6"-8" from surface and spray until thoroughly wet.

Bacteria: Let stand for 60 seconds [-or- 1 minute]. Wipe with a [damp] cloth [or sponge][or paper towel]. [Kills [effective against] [99.9% of] *{Insert disinfection bacteria from Table A}.*]

Bacteria, Viruses[†], [and] Fungi [and mold & mildew]: Let stand for 5 minutes. Wipe with a [damp] cloth [or sponge][or paper towel]. [Kills [effective against] [99.9% of] *{Insert disinfection bacteria, viruses and/or fungi from Table A}.*]

{Mildew Fungistatic Directions}

TO PREVENT MOLD [AND MILDEW] [growth]:

[Fabric Mildewstat] On [cotton and polyester] Fabrics:

[To inhibit mold and mildew growth]: Apply to fabric surface until wet [do not saturate]. Allow to air dry. Repeat [application] every 28 days to inhibit mold [and mildew] growth. [Effective against *Aspergillus niger* [(black mold)] [mildew] and *Penicillium variable*.] Pre-clean heavily soiled surfaces.

[Hard Surface Mildewstat] On hard surfaces:

[To inhibit mold and mildew growth]: Thoroughly wet surface. Allow to air dry. Repeat [application] every 7 days to inhibit mold [and mildew] growth. [Effective against *Aspergillus niger* [(black mold)] [mildew]] Pre-clean heavily soiled surfaces.

III COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 498987-13, "AOAC Germicidal Spray Method," Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538) for Phoenix 2, Lot KK005-111, Lot KK005-112, and Lot KK005-113. Study conducted at Accuratus Lab Services by Melissa Bruner. Study completion date – April 11, 2016. Project Number A20166.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot KK005-111, Lot KK005-112, and Lot KK005-113) of the product, Phoenix 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.GS.1 (copy provided). The product was received ready-to-use as an aerosol spray. A loop of stock slant culture was transferred to an initial 10 mL tube of growth medium. The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, without vortex mixing the *Pseudomonas aeruginosa* culture, a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). Four additional daily transfers were prepared for the *Pseudomonas* culture, and two additional transfers were made for the *Salmonella* culture tested on 02/24/16. The final test cultures were incubated for 48 hours at 35-37°C. During culture transfers, the *Pseudomonas* culture was not vortex mixed. On the day of use, the pellicle was carefully aspirated from the *Pseudomonas aeruginosa* culture by vacuum aspiration. Care was taken to avoid disrupting the pellicle and any visible pellicle on the bottom of the tube was not harvested. To avoid harvesting any visible pellicle at the bottom of the tube, the upper portion of the culture was transferred to a sterile tube. Any culture with disrupted pellicle was not used. Each test culture was vortex mixed (3-4 seconds) and allowed to stand ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The *Pseudomonas* culture was visually inspected to ensure no pellicle fragments were present. The *Pseudomonas* culture was diluted using sterile growth medium by combining 2.00 mL of test organism suspension with 2.00 mL of sterile growth medium. The *Salmonella* and *Staphylococcus* cultures were each diluted using sterile growth medium by combining 1.00 mL of test organism suspension with 4.0 mL of sterile growth medium. The final test cultures were mixed thoroughly prior to use. A 0.20 mL aliquot of FBS was added to 3.80 mL of the *Pseudomonas* prepared culture to yield a 5% fetal bovine serum organic soil load. A 0.10 mL aliquot of FBS was added to 1.90 mL of each prepared culture for *Salmonella* and *Staphylococcus* to yield a 5% fetal bovine serum organic soil load on 02/01/16. No organic soil load was required for testing on 02/24/16. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36.2-36.6°C) and at 50.7-53.4% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface for 2 seconds. The carriers were allowed to remain wet for 1 minute at room temperature (20-21°C) and at 10-26% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the

individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Lethen Broth + 0.28% Lecithin + 2% Tween 80 to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

2. MRID 498987-14, "AOAC Germicidal Spray Method," Test Organism: *Enterobacter aerogenes* (ATCC 13048), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Jamie Herzan. Study completion date – April 20, 2016. Project Number A20432.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048). Two lots (Lot KK005-111 and Lot KK005-112) of the product, Phoenix 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.GS.2 (copy provided). The product was received ready-to-use as an aerosol spray. A loop of stock slant culture was transferred to an initial 10 mL tube of growth medium. The tube was mixed and the initial culture was incubated for 24±2 hours at 25-30°C. Following incubation a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). For testing performed on 3/16/16, four additional daily transfers were prepared. The final test culture was incubated for 48-54 hours at 25-30°C. The test culture was vortex mixed (3-4 seconds) and allowed to stand ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. For testing performed on 3/16/16, the culture was diluted using sterile growth medium by combining 1.00 mL of test organism suspension with 49.0 mL of sterile growth medium. For testing performed on 4/7/16, the culture was diluted using sterile growth medium by combining 1.00 mL of test organism suspension with 54.0 mL of sterile growth medium. The final test culture was mixed thoroughly prior to use. No organic soil was added to the test culture. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 32-35 minutes at 35-37°C (36.5°C) and at 53.0-53.4% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface for 2-3 seconds. For testing performed on 3/16/16, a spray time of 1-2 seconds or until thoroughly wet (2 seconds used) was used. For testing performed on 4/7/16, a spray time of 2-3 seconds or until thoroughly wet (3 seconds used) was used. The carriers were allowed to remain wet for 1 minute at room temperature (21-23.3°C) and at 20-33% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Lethen Broth + 0.28% Lecithin + 2% Tween 80 to neutralize. All subcultures were incubated for 48±2 hours at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

3. MRID 498987-15, "AOAC Germicidal Spray Method," Test Organism: *Escherichia coli* O157:H7 (ATCC 43888), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Carrie K. Bauer. Study completion date – April 11, 2016. Project Number A20421.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 43888). Two lots (Lot KK005-111 and Lot KK005-112) of the product, Phoenix 2, were tested using Accuratus

Laboratory Services Protocol No. WMB002120715.GS.3 (copy provided). The product was received ready-to-use as an aerosol spray. A loop of stock slant culture was transferred to an initial 10 mL tube of growth medium. The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). The test culture was vortex mixed (3-4 seconds) and allowed to stand ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The culture was diluted using sterile growth medium by combining 1.00 mL of test organism suspension with 49.0 mL of sterile growth medium. For testing performed on 4/7/16, the culture was diluted using sterile growth medium by combining 1.00 mL of test organism suspension with 1.00 mL of sterile growth medium. The final test culture was mixed thoroughly prior to use. No organic soil was added to the test culture. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36.6 – 36.7°C) and at 52.54% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface for 2 seconds. The carriers were allowed to remain wet for 1 minute at room temperature (19°C) and at 47% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Letheen Broth + 0.28% Lecithin + 2% Tween 80 to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

4. MRID 498987-16, “AOAC Germicidal Spray Method,” Test Organism: *Listeria monocytogenes* (ATCC 19117), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Carrie K. Bauer. Study completion date – April 11, 2016. Project Number A20420.

This study was conducted against *Listeria monocytogenes* (ATCC 19117). Two lots (Lot KK005-111 and Lot KK005-112) of the product, Phoenix 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.GS.4 (copy provided). The product was received ready-to-use as an aerosol spray. A loop of stock slant culture was transferred to an initial 10 mL tube of growth medium. The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). One additional daily transfer was prepared. The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed (3-4 seconds) and allowed to stand ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The culture was diluted using sterile growth medium by combining 2.00 mL of test organism suspension with 2.00 mL of sterile growth medium. The final test culture was mixed thoroughly prior to use. No organic soil was added to the test culture. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36.5 – 36.6°C) and at 50.4% relative humidity. Carriers were used within 2 hours of drying.

Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface for 2 seconds. The carriers were allowed to remain wet for 1 minute at room temperature (19°C) and at 49% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Letheen Broth + 0.28% Lecithin + 2% Tween 80 to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

5. MRID 498987-17, "AOAC Germicidal Spray Method," Test Organism: Methicillin Resistant *Staphylococcus aureus* – MRSA (ATCC 33592), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Carrie K. Bauer. Study completion date – April 11, 2016. Project Number A20422.

This study was conducted against Methicillin Resistant *Staphylococcus aureus* – MRSA (ATCC 33592). Two lots (Lot KK005-111 and Lot KK005-112) of the product, Phoenix 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.GS.6 (copy provided). The product was received ready-to-use as an aerosol spray. A loop of stock slant culture was transferred to an initial 10 mL tube of growth medium. The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). One additional daily transfer was prepared. The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed (3-4 seconds) and allowed to stand ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The culture was diluted using sterile growth medium by combining 1.00 mL of test organism suspension with 39.0 mL of sterile growth medium. The final test culture was mixed thoroughly prior to use. No organic soil was added to the test culture. Antibiotic susceptibility testing was performed by Accuratus Lab Services for Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592) to verify the antimicrobial resistance pattern stated. The Kirby Bauer susceptibility assay was performed utilizing a representative culture from the day of testing. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36.2 – 36.6°C) and at 53.5% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface for 2 seconds. The carriers were allowed to remain wet for 1 minute at room temperature (20°C) and at 50% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Letheen Broth + 0.28% Lecithin + 2% Tween 80 to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

6. MRID 498987-18, "AOAC Germicidal Spray Method," Test Organism: *Streptococcus pyogenes* (ATCC 12384), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Carrie K. Bauer. Study completion date – April 1, 2016. Project Number A20409.

This study was conducted against *Streptococcus pyogenes* (ATCC 12384). Two lots (Lot KK005-111 and Lot KK005-112) of the product, Phoenix 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.GS.5 (copy provided). The product was received ready-to-use as an aerosol spray. A culture of the test organism was prepared by using a stock culture to inoculate multiple agar plates and incubating for three days at 35-37°C in 6% CO₂. Following incubation, an organism suspension was prepared in Fluid Thioglycollate Medium to target 1 x 10⁸ CFU/mL. A spec value of 1.241 at 620 nm was prepared. The final test culture was mixed thoroughly prior to use. No organic soil was added to the test culture. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 25-30°C (27.0°C) and at 66% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface for 2 seconds. The carriers were allowed to remain wet for 1 minute at room temperature (20°C) and at 45% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Brain Heart Infusion Broth + 0.28% Lecithin + 2% Tween 80 to neutralize. All subcultures were incubated for three days at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

7. MRID 498987-19, "Fungicidal Germicidal Spray Method," Test Organism: *Trichophyton mentagrophytes* (ATCC 9533), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Melissa Bruner. Study completion date – March 11, 2016. Project Number A20163.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot KK005-111 and Lot KK005-112) of the product, Phoenix 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120815.FGS.1 (copy provided). The product was received ready-to-use as an aerosol spray. A culture of *Trichophyton mentagrophytes* was prepared by inoculating 30 agar plates using a stock culture and incubating at 25-30°C for 10 days. The mycelia were removed from sufficient plates using a sterile device. The mycelia were transferred to sterile glassware containing glass beads at a ratio of 25.0 mL of saline/Triton Solution (0.85% saline + 0.05% Triton X-100) per 5 plates harvested, and agitated. The culture was filtered through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemocytometer. The viable cell count was 4.7 x 10⁸ CFU/mL. The culture was stored at 2-8°C for 9 days prior to use. The test culture was diluted by adding 1.00 mL of culture to 14.0 mL of 0.85% saline + 0.05% Triton X-100 solution and was thoroughly mixed prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of each prepared culture to yield a 5% fetal bovine serum organic soil load. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36.5-36.6°C) and at 50.4% relative humidity. Carriers were used within 2 hours of drying. For each lot of prepared test substance, test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface for 2 seconds. The carriers were allowed to remain wet for 5 minute at room temperature (20.9°C) and at 18.2% relative humidity. Following the exposure period, excess liquid was drained off the

carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize. All subcultures were incubated for 10 days at 25-30°C. The agar plate subcultures were incubated for 66-76 hours at 25-30°C. Subcultures were stored at 2-8°C for 2 days prior to examination (see protocol deviation). Following incubation and storage, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

8. MRID 498987-20, "Fungicidal Germicidal Spray Method," Test Organism: *Aspergillus niger* (ATCC 6275), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Maggie Brusky. Study completion date – March 31, 2016. Project Number A20303.

This study was conducted against *Aspergillus niger* (ATCC 6275). Two lots (Lot KK005-111 and Lot KK005-112) of the product, Phoenix 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120815.FGS.2 (copy provided). The product was received ready-to-use as an aerosol spray. The *Aspergillus niger* conidial suspension was prepared by inoculating a flask of Sabouraud Agar (Modified) with the stock culture and incubated for 8 days at 25-30°C. Following incubation, saline/Triton Solution (0.85% saline + 0.05% Triton X-100) and sterile glass beads were added to the flask. The flask was agitated to remove mycelia/conidia from the agar. The conidia suspension was aspirated from the flask and passed through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The viable cell count was 1.38×10^7 CFU/mL. The culture was centrifuge concentrated at 3390 RPM for 15 minutes. A total of 10.0 mL of culture was concentrated to 2.0 mL. The test culture was thoroughly mixed prior to use. A 0.100 mL aliquot of FBS was added to 1.9 mL of prepared culture to yield a 5% Fetal Bovine Serum organic soil load. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36.4-36.5°C) and at 50.3% relative humidity. Carriers were used within 2 hours of drying. For each lot of prepared test substance, test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface for 2 seconds. The carriers were allowed to remain wet for 5 minute at room temperature (23.5°C) and at 17.7% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize. All subcultures were incubated for 10 days at 25-30°C. The agar plate subcultures were incubated for 44.52 hours at 25-30°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

9. MRID 498987-21, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Human Coronavirus (ATCC VR-740, Strain 229E), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Mary J. Miller. Study completion date – April 14, 2016. Project Number A20418.

This study was conducted against Human Coronavirus, ATCC VR-740, Strain 229E, for two lots of Phoenix 2, Lot numbers KK005-111 and KK005-112. These were tested using

Accuratus Lab Services Protocol No. WMB002122915.COR (copy provided). The product was received ready-to-use as an aerosol spray. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 1% fetal bovine serum (FBS) as the organic soil load. Indicator cell cultures of WI-38 (Human lung) cells (ATCC CCL-75) demonstrated cytopathic effects (CPE) typical of Human Coronavirus on WI-38 cells. WI-38 indicator cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere at 5-7% CO₂. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 2% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of spray released under use conditions for a contact time of one minute. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The 10⁻¹ dilution for each lot of test substance was passed through a second individual Sephadex column utilizing the syringe plunger. The filtrates (10⁻¹ dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The WI-38 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 31-35°C in a humidified atmosphere of 5-7% CO₂ in sterile disposable cell culture labware. The cultures were scored periodically for 10 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

10. MRID 498987-22, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus," Test Organism: Feline Calicivirus, F-9 strain (ATCC VR-782), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Melissa Bruner. Study completion date – April 19, 2016. Project Number A20296.

This study was conducted against Feline Calicivirus, F-9 strain (ATCC VR-782), for two lots of Phoenix 2, Lot numbers KK005-111 and KK005-112. These were tested using Accuratus Lab Services Protocol No. WMB002021016.FCAL (copy provided). The product was received ready-to-use as an aerosol spray. Testing was originally performed on 02/24/16. A 3-log reduction beyond the cytotoxic level was not demonstrated, and therefore, the assay was invalid. The assay was repeated on 03/18/16, resulting in valid data. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 1% fetal bovine serum (FBS) as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Feline Calicivirus on Grandel Reese feline kidney cells. Cultures of Grandel Reese feline kidney (CRFK) cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO₂. The confluency of the cells was appropriate for the test virus. The test medium used for this assay was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat inactivated fetal bovine serum. The medium was also supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL

amphotericin B. Dried virus films were prepared by spreading 200 μ L of test virus inoculum uniformly over the bottoms of 6 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of spray released under use conditions for a contact time of 5 minutes. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The 10^{-1} dilution for each lot of test substance was passed through a second individual Sephadex column utilizing the syringe plunger. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The CRFK cell line, which exhibits cytopathic effect (CPE) in the presence of Feline Calicivirus, was used as the indicator cell line in the infectivity assays. The cells in multiwell culture dishes were inoculated in quadruplicate with 100 μ L of the dilutions prepared from test and control groups and were incubated at 31-35°C in a humidified atmosphere of 5-7% CO₂ in sterile disposable cell culture labware. The cultures were microscopically scored periodically for 10 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

11. MRID 498987-23, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Herpes simplex virus type 1 (ATCC VR-733, Strain F(1)), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Melissa Bruner. Study completion date – April 19, 2016. Project Number A20428.

This study was conducted against Herpes simplex virus type 1 (ATCC VR-733, Strain F(1)), for two lots of Phoenix 2, Lot numbers KK005-111 and KK005-112. These were tested using Accuratus Lab Services Protocol No. WMB002120715.HSV1.2 (copy provided). The product was received ready-to-use as an aerosol spray. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 1% fetal bovine serum (FBS) as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Herpes simplex virus on Vero cells. Cultures of Vero cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO₂. The confluency of the cells was appropriate for the test virus. The test medium used for this assay was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat inactivated fetal bovine serum. The medium was also supplemented with 10 μ g/mL gentamicin, 100 units/mL penicillin and 2.5 μ g/mL amphotericin B. Dried virus films were prepared by spreading 200 μ L of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of spray released under use conditions for a contact time of 1 minute. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance

mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The 10^{-1} dilution for each lot of test substance was passed through a second individual Sephadex column utilizing the syringe plunger. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The Vero cell line, which exhibits cytopathic effect (CPE) in the presence of Herpes simplex virus type 1, was used as the indicator cell line in the infectivity assays. The cells in multiwell culture dishes were inoculated in duplicate with 100 μ L of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂ in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

12. MRID 498987-24, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Herpes simplex virus type 2 (ATCC VR-734, Strain G), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Melissa Bruner. Study completion date – April 19, 2016. Project Number A20429.

This study was conducted against Herpes simplex virus type 2 (ATCC VR-734, Strain G), for two lots of Phoenix 2, Lot numbers KK005-111 and KK005-112. These were tested using Accuratus Lab Services Protocol No. WMB002120715.HSV2.2 (copy provided). The product was received ready-to-use as an aerosol spray. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 1% fetal bovine serum (FBS) as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Herpes simplex virus on Vero cells. Cultures of Vero cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO₂. The confluency of the cells was appropriate for the test virus. The test medium used for this assay was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat inactivated fetal bovine serum. The medium was also supplemented with 10 μ g/mL gentamicin, 100 units/mL penicillin and 2.5 μ g/mL amphotericin B. Dried virus films were prepared by spreading 200 μ L of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of spray released under use conditions for a contact time of 1 minute. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The 10^{-1} dilution for each lot of test substance was passed through a second individual Sephadex column utilizing the syringe plunger. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The Vero cell line, which exhibits cytopathic effect (CPE) in the presence of Herpes simplex virus type 2, was used as the indicator cell line in the infectivity assays. The cells in multiwell culture dishes were inoculated in quadruplicate with 100 μ L of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂ in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

13. MRID 498987-25, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: 2009-H1N1 Influenza A virus (Novel H1N1) (Strain A/Mexico/4108/2009 CDC #2009712192), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Melissa Bruner. Study completion date – April 19, 2016. Project Number A20440.

This study was conducted against 2009-H1N1 Influenza A virus (Novel H1N1) (Strain A/Mexico/4108/2009 CDC #2009712192), for two lots of Phoenix 2, Lot numbers KK005-111 and KK005-112. These were tested using Accuratus Lab Services Protocol No. WMB002120715.FLUA.2 (copy provided). The product was received ready-to-use as an aerosol spray. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 1% fetal bovine serum (FBS) as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Influenza virus (Novel H1N1) on MDCK (canine kidney) cells. Cultures of MDCK cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO₂. The confluency of the cells was appropriate for the test virus. The test medium used for this assay was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat inactivated fetal bovine serum. The medium was also supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B, 2 µg/mL TPCK-Trypsin, 25 mM Hepes, and 0.2% BSA fraction V. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 18.9% for 21 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of spray released under use conditions for a contact time of 1 minute. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The 10⁻¹ dilution for each lot of test substance was passed through a second individual Sephadex column utilizing the syringe plunger. The filtrates (10⁻¹ dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The MDCK cell line, which exhibits cytopathic effect (CPE) in the presence of Influenza virus, was used as the indicator cell line in the infectivity assays. The cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂ in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

14. MRID 498987-26, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Respiratory syncytial virus (ATCC VR-26, Strain Long), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Melissa Bruner. Study completion date – April 20, 2016. Project Number A20431.

This study was conducted against Respiratory syncytial virus (ATCC VR-26, Strain Long), for two lots of Phoenix 2, Lot numbers KK005-111 and KK005-112. These were tested using

Accuratus Lab Services Protocol No. WMB002120715.RSV.2 (copy provided). The product was received ready-to-use as an aerosol spray. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 1% fetal bovine serum (FBS) as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Respiratory syncytial virus (RSV) on Hep-2 (human larynx carcinoma) cells. Cultures of Hep-2 cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO₂. The confluency of the cells was appropriate for the test virus. The test medium used for this assay was Minimum Essential Medium (MEM) supplemented with 2% (v/v) heat inactivated fetal bovine serum. The medium was also supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, 1.0 mM L-glutamine, and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of spray released under use conditions for a contact time of 1 minute. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The 10⁻¹ dilution for each lot of test substance was passed through a second individual Sephadex column utilizing the syringe plunger. The filtrates (10⁻¹ dilution) were titrated by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The Hep-2 cell line, which exhibits cytopathic effect (CPE) in the presence of Respiratory syncytial virus (RSV), was used as the indicator cell line in the infectivity assays. The cells in multiwell culture dishes were inoculated in duplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂ in sterile disposable cell culture labware. The cultures were scored periodically for 9 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

15. MRID 498987-27, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Rhinovirus type 39 (ATCC VR-340, Strain 209), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Melissa Bruner. Study completion date – April 20, 2016. Project Number A20430.

This study was conducted against Rhinovirus type 39 (ATCC VR-340, Strain 209), for two lots of Phoenix 2, Lot numbers KK005-111 and KK005-112. These were tested using Accuratus Lab Services Protocol No. WMB002120715.R39.2 (copy provided). The product was received ready-to-use as an aerosol spray. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 1% fetal bovine serum (FBS) as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Rhinovirus type 39 on WI-38 (human lung) cells. Cultures of WI-38 (human lung) cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO₂. The confluency of the cells was appropriate for the test virus. The test medium used for this assay was Minimum Essential Medium (MEM) supplemented with 10% (v/v) heat inactivated fetal bovine serum. The medium was also supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Dried virus films were

prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 15.5°C in a relative humidity of 50% for 20 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of spray released under use conditions for a contact time of 5 minute. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The 10⁻¹ dilution for each lot of test substance was passed through a second individual Sephadex column utilizing the syringe plunger. The filtrates (10⁻¹ dilution) were titrated by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The WI-38 (human lung) cell line, which exhibits cytopathic effect (CPE) in the presence of Rhinovirus type 39, was used as the indicator cell line in the infectivity assays. The cells in multiwell culture dishes were inoculated in duplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 31-35°C in a humidified atmosphere of 5-7% CO₂ in sterile disposable cell culture labware. The cultures were scored periodically for 10 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

16. MRID 498987-28, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Rotavirus (ATCC VR-2018, Strain WA), for Phoenix 2, Lot KK005-111 and Lot KK005-112. Study conducted at Accuratus Lab Services by Mary J. Miller. Study completion date – April 4, 2016. Project Number A20408.

This study was conducted against Rotavirus (ATCC VR-2018, Strain WA), for two lots of Phoenix 2, Lot numbers KK005-111 and KK005-112. These were tested using Accuratus Lab Services Protocol No. WMB002120715.ROT.2 (copy provided). The product was received ready-to-use as an aerosol spray. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus contained no organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Rotavirus on MA-104 cells. Cultures of MA-104 (Rhesus monkey kidney) cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO₂. The confluency of the cells was appropriate for the test virus. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 0.5 µg/mL trypsin and 2.0 mM L-glutamine. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 40% for 20 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of spray released under use conditions for a contact time of 5 minute. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The 10⁻¹ dilution for each lot of test substance was

passed through a second individual Sephadex column utilizing the syringe plunger. The filtrates (10^{-1} dilution) were titrated by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The MA-104 cell line, which exhibits cytopathic effect (CPE) in the presence of Rotavirus, was used as the indicator cell line in the infectivity assays. The cells in multiwell culture dishes were inoculated in quadruplicate with 100 μ L of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂ in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

17. MRID 498987-29, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)," Test Organisms: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538), for Phoenix 2, Lot KK005-111, Lot KK005-112, and KK005-113. Study conducted at Accuratus Lab Services by Jamie Herzan. Study completion date – March 8, 2016. Project Number A20176.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot KK005-111, Lot KK005-112, and Lot KK005-113) of the product, Phoenix 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.NFS.2 (copy provided). The product was received ready-to-use as an aerosol spray. From a stock slant no more than 5 transfers from original stock and ≤ 1 month old, an initial tube (10 mL) of culture broth was inoculated. This culture was termed the "initial broth suspension." From this initial broth suspension, a minimum of three daily transfers using 1 loopful (10 μ L) of culture into 10 mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24 \pm 2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ~15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The *Enterobacter aerogenes* culture was diluted using sterile growth medium by combining 1.00 mL of test organism suspension with 4.00 mL of sterile growth medium. The *Staphylococcus aureus* culture was diluted using sterile growth medium by combining 3.00 mL of test organism suspension with 3.00 mL of sterile growth medium. The cultures were thoroughly mixed prior to use. A 0.20 mL aliquot of FBS was added to 3.80 mL of each prepared culture to yield a 5% fetal bovine serum organic soil load. Sterile carriers were inoculated with 0.02 mL (20.0 μ L) of culture using a calibrated pipettor spreading the inoculum to within approximately 3 mm of the edges of the carrier. The inoculated carriers were dried for 20 minutes at 35-37°C (36.1-36.3°C) and 40-41% relative humidity with the Petri dish lids slightly ajar. Following the completion of drying, each of the five test carriers were sprayed with test substance using staggered intervals. Carriers were sprayed at a distance of 6-8 inches for 1-2 seconds or until thoroughly wet (2 seconds used) and were allowed to expose at room temperature (20°C) and 22% relative humidity for 10 seconds. Following exposure, each carrier was transferred to 20 mL of neutralizer using identical staggered intervals. Following the neutralization of the test carriers, the excess liquid in each Petri dish was transferred to the neutralizer jar containing the matching carrier. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10^0) were plated onto the recovery agar plate medium. The *S. aureus* plates were incubated at 35-37°C for 48 \pm 4 hours. The *E. aerogenes* plates were incubated for 48 \pm 4 hours at 25-32°C. The subcultures were placed at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were visually enumerated. Controls included those for carrier population, media sterility, culture purity, neutralization confirmation, and inoculum count.

18. MRID 498987-30, "Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces (with exposure and wear activity)," Test Organisms: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538), for Phoenix 2, Lot KK005-111, Lot KK005-112, and KK005-113. Study conducted at Accuratus Lab Services by Matthew Sathe. Study completion date – April 1, 2016. Project Number A20268.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot KK005-111, Lot KK005-112, and Lot KK005-113) of the product, Phoenix 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.RES.2 (copy provided). The product was received ready-to-use as an aerosol spray. From a stock slant an initial tube (10 mL) of culture broth was inoculated. This culture was termed the "initial broth suspension." From this initial broth suspension, a minimum of three daily transfers using 1 loopful (10 µL) of culture into 10 mL of culture media were performed on consecutive days prior to use in testing procedure.

For the initial inoculation culture, a 48-54 hour culture, per test organism, was vortex mixed and was allowed to stand for 15±1 minutes. Using the upper 2/3rds of inoculum, the culture was serially diluted by adding 0.100 mL of culture to 9.9 mL of sterile deionized water. This serial dilution was repeated a second time yielding a total of two 1:100 dilutions. The concentration of each final (diluted) initial inoculation culture was determined by serial dilution and standard plating technique (initial suspension control). A 0.20 mL aliquot of FBS was added to 3.80 mL of diluted culture to yield a 5% fetal bovine serum organic soil load. The final culture was mixed and allowed to stand at least 15±1 minutes prior to use.

For the reinoculation culture, an 18-24 hour culture, per test organism, was vortex mixed and was allowed to stand for 15±1 minutes. Using the upper 2/3rds of inoculum, the culture was serially diluted by adding 0.100 mL of culture to 9.9 mL of sterile deionized water. This serial dilution was repeated a second time yielding a total of two 1:100 dilutions. Finally, the culture was diluted 1:2 by combining 5.0 mL of culture with 5.0 mL of sterile deionized water. The concentration of each final (diluted) 18-24 hour reinoculation culture was determined by serial dilution and standard plating technique (initial suspension control). A 0.30 mL aliquot of FBS was added to 5.70 mL of diluted culture to yield a 5% fetal bovine serum organic soil load. The final culture was mixed and allowed to stand at least 15±1 minutes prior to use. No culture with organic soil load was allowed to stand >8 hours prior to use.

For the sanitizer test culture, an 18-24 hour culture, per test organism, was vortex mixed and was allowed to stand for at least 15±1 minutes. The upper 2/3rds of inoculum was removed by aspiration for inoculation. To target 5.88-6.38 log₁₀/carrier, the *Enterobacter aerogenes* culture was diluted 1:8 in tryptic soy broth and *Staphylococcus aureus* was not diluted. The concentration of each sanitizer test culture was determined by serial dilution and standard plating technique (initial suspension control). A 0.20 mL aliquot of FBS was added to 3.80 mL of prepared culture to yield a 5% fetal bovine serum organic soil load. The final culture was mixed and allowed to stand at least 15±1 minutes prior to use.

Initial Inoculation Procedure

Using the prepared initial inoculation culture, a 10.0 µL aliquot was applied to each test and numbers control carrier, spreading the inoculum with a bent needle (hook) to within approximately

1/8th inch from the edge of the carrier. The carriers were dried, with the Petri dish lids slightly ajar, at 35-37°C for 30 minutes, until visibly dry.

Application of the Test and Control Substance

To avoid filter paper buckling in the Petri dish, 4 square glass carriers were placed inside a glass Petri dish with 1 piece of Whatman filter paper, weighed down by sterile stainless steel carriers. The test substance was then applied to all 4 replicate carriers (in the same dish) by spraying for 2 seconds onto the center of the petri dish at a 45° angle, with the nozzle of the sprayer 6"-8" above the carrier surface. The treated carriers were dried uncovered in an environmental chamber set at 20°C and 48% relative humidity (RH) targeting 20-23°C and 45-48% RH (21.0°C and 46-48% RH) for 19 hours and 30 minutes, until completely dry. Similarly, a sterile solution of 0.01% Triton-X-100 solution was applied to each inoculated, dried numbers control carrier using 3 pumps from a trigger sprayer held at a 6-8" distance. The control carriers were allowed to dry as described for the test carriers. Inoculated, treated and dried test and numbers control carriers underwent a wear and reinoculation regimen, which took place over ≥24 hours at ambient temperature and humidity conditions. Two carriers underwent the wearing procedure simultaneously, per abrasion boat. The abrasion boat apparatus was assembled with sufficient weights, a foam liner and a sterile cotton liner such that the actual weight of the assembled boat was equal to 1084±1 g. Glass 4"x4" spacers were used on the wear tester and changed out every wear for disinfected spacers. The spacers were dry wiped before each wear. The actual weight of the abrasion boat assembly was recorded each time it was assembled and used. Only one weigh boat was used at a time during wears. In between wear cycle sets, the abrasion boat apparatus was disassembled and the cotton liner was replaced with a fresh, sterile cotton liner. The foam liner was replaced as needed and between organisms. Additionally, the abrasion tester was decontaminated with absolute ethanol in between cycle sets allowing the alcohol to completely evaporate before re-use. Alternating dry and wet cycles were performed. Wet wear cycles were performed by wetting the cotton liner attached to the weight boat assembly with sterile deionized water, using a Preval sprayer (or equivalent). This was achieved by misting the liner from a distance of approximately 75±1 cm for less than or equal to one second. Immediately after wetting, the moistened abrasion boat was attached to the abrasion tester and was used.

Reinoculation procedure

After an entire wear cycle was complete (i.e. all test and control carriers underwent the wear procedure), each test and numbers control carrier was reinoculated. Reinoculation occurred ~15 minutes after the wear procedure was performed for the given carrier. Using the prepared reinoculation culture inoculum, a 10.0 µL aliquot was applied to each carrier spreading to within approximately 1/8th inch from the edge of the carrier. The reinoculated carriers were uncovered and dried for ~30 minutes in an environmental chamber set at 20°C and 48% RH, prior to initiating the next wear cycle or the sanitizer test. Carriers were not reinoculated following the final wear cycle. A total of 12 wear cycles alternated by 5 reinoculations were performed. Actual ambient conditions were periodically measured during the wear and reinoculation procedure.

During the wear procedure, the temperature was 20°C and the relative humidity range was 15-16%.

Sanitizer Test

At least 15 minutes after the final wear cycle (and at least 24 hours after test substance application), the sanitizer test was initiated. Using the prepared sanitizer test culture, each test and numbers control carrier was inoculated with 10.0 µl of culture spreading the inoculum with a bent needle (hook) to within approximately 1/8th inch from the edge of the carrier. The culture was applied at staggered intervals using a calibrated timer. The carriers were allowed to expose at ambient conditions (20°C and 20% relative humidity) for 4.5 minutes. Exposure began for each

carrier as it was inoculated. Once the exposure period was achieved, each test and numbers control carrier was subcultured (at identical staggered intervals) into 30 mL of neutralizer broth using sterile forceps (representing a 10^0 dilution). This was continued until all test and numbers control carriers were subcultured. Following subculturing, each subculture was sonicated for 20 seconds. Each sonicated subculture was mixed on an orbital shaker for 3 minutes set to approximately 250 RPM. Within 30 minutes of neutralization, ten-fold serial dilutions were prepared using a sterile diluent. For the test subcultures, 1.00 mL aliquots of 10^0 through 10^{-3} were pour-plated in duplicate onto the recovery agar plate medium. For the numbers control carriers, 1.00 mL aliquots of 10^{-1} through 10^{-4} were pour-plated in duplicate onto the recovery agar plate medium.

Incubation and Observation

Plates and controls were incubated for 48-54 hours, at 35-37°C for *S. aureus* and 28-32°C for *E. aerogenes*. Subcultures from 2/18/16 were placed at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were visually examined for growth. If possible, plates containing between 30 and 300 CFU were counted. On 2/22/16, representative test and positive control subcultures showing growth were visually examined, Gram stained, and biochemically assayed to confirm or rule out the presence of the test organism.

19. MRID 498987-31, "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application)," Test Organisms: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538), for Phoenix 2, Lot KK005-111, Lot KK005-112, and KK005-113. Study conducted at Accuratus Lab Services by Jamie Herzan. Study completion date – April 11, 2016. Project Number A20190.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot KK005-111, Lot KK005-112, and Lot KK005-113) of the product, Phoenix 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.NFS.3 (copy provided). The product was received ready-to-use as an aerosol spray. Carriers – fabric squares; two fabric types: For the plain 100% cotton weave fabric (containing approximately 80 x 80 threads/inch), a scouring solution was prepared by adding 1.75 grams Na_2CO_3 and 1.75 grams of Triton X-100 to 3.5 L of deionized water. Then 355 grams of test fabric was added to 3.5 L of scouring solution. For the 100% polyester fabric, a scouring solution was prepared by adding 0.80 grams Na_2CO_3 and 0.80 grams of Triton X-100 to 1.6 L of deionized water. Then 160 grams of test fabric was added to 1.6 L of scouring solution. For both fabric types, the scouring solution was allowed to boil for approximately 60 minutes. The fabric was removed and was rinsed by first placing the fabric into boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The carriers were cut from the fabric to a size of approximately 1 inch x 1 inch and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. From a stock slant no more than 5 transfers from original stock and ≤ 1 month old, an initial tube (10 mL) of culture broth was inoculated. This culture was termed the "initial broth suspension." From this initial broth suspension, a minimum of three daily transfers using 1 loopful (10 μL) of culture into 10 mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24 ± 2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥ 15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The *Enterobacter aerogenes* culture used to inoculate the polyester fabric carriers was diluted using sterile growth medium by combining 2.00 mL of test organism suspension with 2.00 mL of sterile

growth medium. The *Staphylococcus aureus* culture used to inoculate the cotton fabric carriers was centrifuge concentrated at 3500 RPM for 10 minutes. A total of 20.0 mL of culture was concentrated to 4.0 mL. The cultures were thoroughly mixed prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of each prepared culture to yield a 5% fetal bovine serum organic soil load. Sterile carriers were inoculated with 0.03 mL of culture using a calibrated pipettor distributing the inoculum evenly about the carrier. The inoculated carriers were dried for 20 minutes at 35-37°C (36.4-36.6°C) and 49.5-53.2% relative humidity with the Petri dish lids intact. Following the completion of drying, each of the five test carriers were sprayed with test substance using staggered intervals. Carriers were sprayed at a distance of 6-8 inches for 1-2 seconds or until thoroughly wet (2 seconds used) and were allowed to expose at room temperature (21°C) and 20% relative humidity for 1 minute. Following exposure, each carrier was transferred to 20 mL of neutralizer using identical staggered intervals. Following the neutralization of the test carriers, the excess liquid in each Petri dish was transferred to the neutralizer jar containing the matching carrier. The carriers were vortex-mixed for 10-15 seconds to ensure complete elution of the test organism. Glass beads were utilized to aid in organism recovery from the modified fabric substrate. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10^0) were plated onto the recovery agar plate medium. The *Staphylococcus aureus* plates were incubated at 35-37°C for 48±4 hours. The *Enterobacter aerogenes* plates were incubated for 48±4 hours at 25-32°C. The subcultures were placed at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were visually enumerated. Controls included those for carrier population, media sterility, culture purity, and neutralization confirmation control.

20. MRID 498987-32, "EPA Hard Surface Mildew-Fungistatic Test," Test Organism: *Aspergillus niger* (ATCC 6275), for Phoenix 2, Lot KK005-111, and Lot KK005-112. Study conducted at Accuratus Lab Services by Jamie Herzan. Study completion date – April 20, 2016. Project Number A20433.

This study was conducted against *Aspergillus niger* (ATCC 6275). Two lots (Lot KK005-111 and Lot KK005-112) of the product, Phoenix 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.MSTAT.2 (copy provided). The product was received ready-to-use as an aerosol spray. A flask of neopeptone agar was inoculated with a conidial suspension of the test organism and incubated 10 days at 25-30°C. After addition of a sterile saline solution/Triton Solution and glass beads, the flask was agitated to remove the mycelia/conidia. Hyphal fragments were removed and the conidial concentration was estimated by counting in a hemacytometer. The conidial count was 5.8×10^7 CFU/mL. The suspension was ground and standardized to contain 5×10^6 conidia/mL by adding 1.00 mL of unadjusted culture to 9.0 mL of sterile saline. A 1.00 mL aliquot of this suspension was added to 20.0 mL sterile Czapek's solution. No organic soil was added to the culture. Ten (10) glazed ceramic tile carriers per product batch were sprayed with the product at a distance of 6 – 8 inches using 3-4 sprays (4 sprays used). The treated carriers were placed in a vertical or near vertical position to permit excess liquid to drain. The carriers were dried in Petri dishes at 35-37°C for 27 minutes with the lids ajar. Untreated carriers were placed in sterile Petri dishes and dried for 20 minutes at 35-37°C with the lids ajar alongside the test carriers. The test organism suspension was sprayed onto the surface of the treated carrier with an atomizer. Approximately 3 sprays were used, and the atomizer was periodically mixed during inoculation. The carriers were dried at 35-37°C for 36 minutes and then transferred to individual water agar plates. Plates were incubated 7 days at 25-30°C in a minimum 95% relative humidity, and then visually examined for growth. Controls included those for purity, sterility, and an untreated control carrier.

21. MRID 498987-33, "Fabric Mildew Fungistatic Test," Test Organisms: *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333), for Phoenix 2, Lot

KK005-111, and Lot KK005-112. Study conducted at Accuratus Lab Services by Matthew Sathe. Study completion date – April 20, 2016. Project Number A20196.

This study was conducted against *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333). Two lots (Lot KK005-111 and Lot KK005-112) of the product, Phoenix 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.FMSTAT.2 (copy provided). The product was received ready-to-use as an aerosol spray. The *Aspergillus niger* conidial suspension was prepared by inoculating a flask of neopeptone agar was inoculated with a conidial suspension of the test organism and incubated 8 days at 25-30°C. After addition of a sterile saline solution/Triton Solution and glass beads, the flask was agitated to remove the mycelia/conidia. Hyphal fragments were removed and the conidial concentration was estimated by counting in a hemacytometer. The viable cell count was 1.38×10^7 CFU/mL. The conidial suspension was standardized to contain an approximate target of 5×10^6 conidia per mL by combining 7.0 mL of culture with 14.0 mL 0.85% saline. The *Penicillium variable* conidial suspension was prepared by inoculating 30 Sabouraud Dextrose agar plates (also known as Emmons agar) and incubating at 25-30°C for 10 days. Following incubation, 3.0 mL of sterile saline/Triton Solution (0.85% Saline + 0.05 % Triton X-100) was added to each plate harvested. The growth was harvested from the agar surface using a cell scraper. The harvested growth was transferred to a sterile vessel containing sterile beads and was hand swirled thoroughly. The culture was then filtered through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The viable cell count was 3.9×10^8 CFU/mL. The conidial suspension was standardized to contain an approximate target of 5×10^6 conidia per mL by combining 1.00 mL of culture with 79.0 mL 0.85% saline. For each lot of test substance, each side of 10 test carriers were sprayed with the test substance at a distance of 6-8 inches for 1-2 seconds (2 seconds). The treated carriers were placed in a vertical or near vertical position to permit excess liquid to drain. The carriers were dried at room temperature (21.7-23.3°C) for 25-38 minutes until dry. Equal volumes (9.5 mL) of each well-mixed conidial suspension were combined within a DeVilbiss atomizer. A 1.00 mL aliquot of FBS was added to the 19.0 mL of combined organism suspension to yield a 5% fetal bovine serum soil load. Both sides of each fabric test carrier strip were lightly sprayed using 5-6 total sprays. The culture was mixed periodically within the atomizer during spraying. The fabric test and control samples were suspended in individual 250 mL French Square bottles containing approximately 10 mL sterile deionized water and incubated at 25-30°C. The caps were tightened and then backed off approximately 1/8 turn to allow for ventilation. It was ensured that no fabric was touching the water at the time of incubation. The control plates and organic soil load sterility control were incubated for 3 days at 25-30°C. Observations were made and recorded every 7 days for four weeks. The presence or absence of observable mold on the test carriers was the criterion for determining the effectiveness of the test product. Where no growth was visually evident at each weekly observation, a magnified examination was conducted to confirm the absence or establish the presence of sub-visual growth. The conidial count was 5.8×10^7 CFU/mL. The suspension was ground and standardized to contain 5×10^6 conidia/mL by adding 1.00 mL of unadjusted culture to 9.0 mL of sterile saline. A 1.00 mL aliquot of this suspension was added to 20.0 mL sterile Czapek's solution. No organic soil was added to the culture. Ten (10) glazed ceramic tile carriers per product batch were sprayed with the product at a distance of 6 – 8 inches using 3-4 sprays (4 sprays used). The treated carriers were placed in a vertical or near vertical position to permit excess liquid to drain. The carriers were dried in Petri dishes at 35-37°C for 27 minutes with the lids ajar. Untreated carriers were placed in sterile Petri dishes and dried for 20 minutes at 35-37°C with the lids ajar alongside the test carriers. The test organism suspension was sprayed onto the surface of the treated carrier with an atomizer. Approximately 3 sprays were used, and the atomizer was periodically mixed during inoculation. The carriers were dried at 35-37°C for 36 minutes and then transferred to individual water agar plates. Plates were incubated 7 days at 25-

30°C in a minimum 95% relative humidity, and then visually examined for growth. Controls included those for purity, sterility, and an untreated control carrier.

IV RESULTS

AOAC Germicidal Spray Products Test Results

MRID	Organism	Organism Designation	Lot No.	No. of Carriers Exhibiting Growth/ Total No. Tested	Carrier Population (Log ₁₀ CFU/ Carrier)
	1-Minute Exposure Time ----- 5% FBS Soil Load				
498987-13	<i>Pseudomonas aeruginosa</i>	ATCC 15442	KK005-111	0/60	5.34
			KK005-112	0/60	
			KK005-113	0/60	
	<i>Salmonella enterica</i>	ATCC 10708	KK005-111	1/60	4.61
			KK005-112	2/60	
			KK005-113	0/60	
	<i>Staphylococcus aureus</i>	ATCC 6538	KK005-111	0/60	5.48
			KK005-112	0/60	
			KK005-113	0/60	
	1-Minute Exposure Time ----- No Soil Load				
498987-14	<i>Enterobacter aerogenes</i>	ATCC 13048	KK005-111	0/10	5.79
			KK005-112	0/10	5.39
498987-15	<i>Escherichia coli</i> O157:H7	ATCC 43888	KK005-111	0/10	5.94
			KK005-112	0/10	
498987-16	<i>Listeria monocytogenes</i>	ATCC 19117	KK005-111	0/10	6.35
			KK005-112	0/10	
498987-17	<i>Staphylococcus aureus</i> – MRSA	ATCC 33592	KK005-111	0/10	5.04
			KK005-112	0/10	
498987-18	<i>Streptococcus pyogenes</i>	ATCC 12384	KK005-111	0/10	5.78
			KK005-112	0/10	
	5-Minute Exposure Time ----- 5% FBS Soil Load				
498987-19	<i>Trichophyton mentagrophytes</i>	ATCC 9533	KK005-111	0/10	4.70
			KK005-112	0/10	
498987-20	<i>Aspergillus niger</i>	ATCC 6275	KK005-111	0/10	4.85
			KK005-112	0/10	

Virucidal Spray Test Method Results

MRID	Organism	Dilutions	Lot No. KK005-111	Lot No. KK005-112	Dried Virus Count
1-Minute Contact Time ----- 1% Organic Soil Added					
498987-21	Human Coronavirus (ATCC VR-733, Strain F(1))	10 ⁻¹ to 10 ⁻⁷ Dilutions	Complete inactivation	Complete inactivation	10 ^{4.75} TCID ₅₀ / 100 µL
		TCID ₅₀ /100 µL	≤10 ^{0.50}	≤10 ^{1.50}	
498987-23	Herpes simplex virus type 1 (ATCC VR-733, Strain F(1))	10 ⁻¹ to 10 ⁻⁷ Dilutions	Complete inactivation	Complete inactivation	10 ^{5.0} TCID ₅₀ / 100 µL
		TCID ₅₀ /100 µL	≤10 ^{0.50}	≤10 ^{0.50}	
498987-24	Herpes simplex virus type 2 (ATCC VR-734, Strain G)	10 ⁻¹ to 10 ⁻⁸ Dilutions	Complete inactivation	Complete inactivation	10 ^{4.50} TCID ₅₀ / 100 µL
		TCID ₅₀ /100 µL	≤10 ^{0.50}	≤10 ^{0.50}	
498987-25	2009-H1N1 Influenza A virus (Novel H1N1) (Strain A/Mexico/4108/2009 CDC #2009712192)	10 ⁻¹ to 10 ⁻⁷ Dilutions	Complete inactivation	Complete inactivation	10 ^{6.00} TCID ₅₀ / 100 µL
		TCID ₅₀ /100 µL	≤10 ^{0.50}	≤10 ^{0.50}	
498987-26	Respiratory syncytial virus (ATCC VR-26, Strain Long)	10 ⁻¹ to 10 ⁻⁷ Dilutions	Complete inactivation	Complete inactivation	10 ^{4.50} TCID ₅₀ / 100 µL
		TCID ₅₀ /100 µL	≤10 ^{0.50}	≤10 ^{0.50}	
5-Minute Contact Time ----- 1% FBS Soil Load					
498987-27	Rhinovirus type 39 (ATCC VR-340, Strain 209)	10 ⁻¹ to 10 ⁻⁷ Dilutions	Complete inactivation	Complete inactivation	10 ^{4.75} TCID ₅₀ / 100 µL
		TCID ₅₀ /100 µL	≤10 ^{0.50}	≤10 ^{0.50}	
5-Minute Contact Time ----- 0% FBS Soil Load					
498987-28	Rotavirus (ATCC VR- 2018, Strain WA)	10 ⁻¹ to 10 ⁻⁸ Dilutions	Complete inactivation	Complete inactivation	10 ^{6.00} TCID ₅₀ / 100 µL
		TCID ₅₀ /100 µL	≤10 ^{1.50}	≤10 ^{1.50}	

Virucidal Spray Test Method Results – Utilizing an MPN Statistical Program

MRID	Organism	Dilutions	Lot No. KK005-111	Lot No. KK005-112	Dried Virus Control (Average)
5-Minute Contact Time ----- 1% Organic Soil Added					
498987-22	Feline Calicivirus* (ATCC VR-782, Strain F-9)	10 ⁻¹ to 10 ⁻⁴ Dilutions	Complete inactivation	Complete inactivation	Log ₁₀ MPN 4.379
		TCID ₅₀ /100 µL	≤10 ^{0.50}	≤10 ^{1.50}	
Log ₁₀ Reduction		≥4.38			

* As a surrogate virus for Norovirus

MRID 498987-29 – Non-Food Contact Surface Sanitizer Testing Results

Test Organism: <i>Enterobacter aerogenes</i> (ATCC 13048)				10 sec. Contact Time		
Test Substance	Carrier #	CFU/Carrier	Log ₁₀	Avg. Log ₁₀	Geometric Mean	Reduction
Lot No. KK005-111	1	<2×10 ¹	<1.30	<1.30	<2.00×10 ¹	>99.9%
	2	<2×10 ¹	<1.30			
	3	<2×10 ¹	<1.30			
	4	<2×10 ¹	<1.30			
	5	<2×10 ¹	<1.30			
Lot No. KK005-112	1	<2×10 ¹	<1.30	<1.30	<2.00×10 ¹	>99.9%
	2	<2×10 ¹	<1.30			
	3	<2×10 ¹	<1.30			
	4	<2×10 ¹	<1.30			
	5	<2×10 ¹	<1.30			
Lot No. KK005-113	1	<2×10 ¹	<1.30	<1.30	<2.00×10 ¹	>99.9%
	2	<2×10 ¹	<1.30			
	3	<2×10 ¹	<1.30			
	4	<2×10 ¹	<1.30			
	5	<2×10 ¹	<1.30			

Test Organism: <i>Staphylococcus aureus</i> (ATCC 6538)				10 sec. Contact Time		
Test Substance	Carrier #	CFU/Carrier	Log ₁₀	Avg. Log ₁₀	Geometric Mean	Reduction
Lot No. KK005-111	1	<2×10 ²	<2.30	<2.30	<2.00×10 ²	>99.9%
	2	<2×10 ²	<2.30			
	3	<2×10 ²	<2.30			
	4	<2×10 ²	<2.30			
	5	<2×10 ²	<2.30			
Lot No. KK005-112	1	<2×10 ²	<2.30	<2.30	<2.00×10 ²	>99.9%
	2	<2×10 ²	<2.30			
	3	<2×10 ²	<2.30			
	4	<2×10 ²	<2.30			
	5	<2×10 ²	<2.30			
Lot No. KK005-113	1	<2×10 ²	<2.30	<2.30	<2.00×10 ²	>99.9%
	2	<2×10 ²	<2.30			
	3	<2×10 ²	<2.30			
	4	<2×10 ²	<2.30			
	5	<2×10 ²	<2.30			

MRID 498987-30 – Residual Self-Sanitizing Activity of Dried Chemical Residues – Results

Test Organism: <i>Enterobacter aerogenes</i> (ATCC 13048)						
Test Substance	Carrier #	CFU/Carrier	Log ₁₀	Avg. Log ₁₀	Geometric Mean	Reduction
Lot No. KK005-111	1	3×10 ¹	1.48	1.80	<6.31×10 ¹	>99.9%
	2	2×10 ²	2.30			
	3	9×10 ¹	1.95			
	4	3×10 ¹	1.48			
Lot No. KK005-112	1	<3×10 ¹	<1.48	<1.60	<3.98×10 ¹	>99.9%
	2	3×10 ¹	1.48			
	3	9×10 ¹	1.95			
	4	<3×10 ¹	<1.48			
Lot No. KK005-113	1	2.6×10 ⁶	6.41	<2.71	<5.13×10 ²	>99.9%
	2	3×10 ¹	1.48			
	3	<3×10 ¹	<1.48			
	4	3×10 ¹	1.48			
Test Organism: <i>Staphylococcus aureus</i> (ATCC 6538)						
Test Substance	Carrier #	CFU/Carrier	Log ₁₀	Avg. Log ₁₀	Geometric Mean	Reduction
Lot No. KK005-111	1	<3×10 ¹	<1.48	<1.48	<3.02×10 ¹	>99.9%
	2	<3×10 ¹	<1.48			
	3	<3×10 ¹	<1.48			
	4	<3×10 ¹	<1.48			
Lot No. KK005-112	1	<3×10 ¹	<1.48	<1.48	<3.02×10 ¹	>99.9%
	2	<3×10 ¹	<1.48			
	3	<3×10 ¹	<1.48			
	4	<3×10 ¹	<1.48			
Lot No. KK005-113	1	<3×10 ¹	<1.48	<1.48	<3.02×10 ¹	>99.9%
	2	<3×10 ¹	<1.48			
	3	<3×10 ¹	<1.48			
	4	<3×10 ¹	<1.48			

Testing Carrier Material: 100% Plain Cotton Weave
 MRID 498987-31 Non-Food Contact Soft Surface Sanitizer Testing Results

Test Organism: <i>Enterobacter aerogenes</i> (ATCC 13048)						
Test Substance	Carrier #	CFU/Carrier	Log ₁₀	Avg. Log ₁₀	Geometric Mean	Reduction
Lot No. KK005-111	1	1.0×10 ⁴	4.00	3.40	2.51×10 ³	>99.9%
	2	2.88×10 ³	3.46			
	3	1.3×10 ³	3.11			
	4	6.8×10 ³	3.83			
	5	4×10 ²	2.60			
Lot No. KK005-112	1	1.0×10 ³	3.00	3.16	1.45×10 ³	>99.9%
	2	4.2×10 ²	2.62			
	3	6.6×10 ³	3.82			
	4	1.2×10 ³	3.08			
	5	1.9×10 ³	3.28			
Lot No. KK005-113	1	1.7×10 ³	3.23	3.18	1.51×10 ³	>99.9%
	2	1.2×10 ³	3.08			
	3	1.2×10 ⁴	4.08			
	4	3.4×10 ²	2.53			
	5	1.0×10 ³	3.00			

Test Organism: <i>Staphylococcus aureus</i> (ATCC 6538)						
Test Substance	Carrier #	CFU/Carrier	Log ₁₀	Avg. Log ₁₀	Geometric Mean	Reduction
Lot No. KK005-111	1	<2×10 ²	<2.30	<2.30	<2.00×10 ²	>99.9%
	2	<2×10 ²	<2.30			
	3	<2×10 ²	<2.30			
	4	<2×10 ²	<2.30			
	5	<2×10 ²	<2.30			
Lot No. KK005-112	1	<2×10 ²	<2.30	<2.30	<2.00×10 ²	>99.9%
	2	<2×10 ²	<2.30			
	3	<2×10 ²	<2.30			
	4	<2×10 ²	<2.30			
	5	<2×10 ²	<2.30			
Lot No. KK005-113	1	<2×10 ²	<2.30	<2.30	<2.00×10 ²	>99.9%
	2	<2×10 ²	<2.30			
	3	<2×10 ²	<2.30			
	4	<2×10 ²	<2.30			
	5	<2×10 ²	<2.30			

Testing Carrier Material: 100% Polyester
 MRID 498987-31 Non-Food Contact Soft Surface Sanitizer Testing Results

Test Organism: <i>Enterobacter aerogenes</i> (ATCC 13048)						
Test Substance	Carrier #	CFU/Carrier	Log ₁₀	Avg. Log ₁₀	Geometric Mean	Reduction
Lot No. KK005-111	1	<2×10 ¹	<1.30	<1.30	<2.00×10 ¹	>99.9%
	2	<2×10 ¹	<1.30			
	3	<2×10 ¹	<1.30			
	4	<2×10 ¹	<1.30			
	5	<2×10 ¹	<1.30			
Lot No. KK005-112	1	<2×10 ¹	<1.30	<1.30	<2.00×10 ¹	>99.9%
	2	<2×10 ¹	<1.30			
	3	<2×10 ¹	<1.30			
	4	<2×10 ¹	<1.30			
	5	<2×10 ¹	<1.30			
Lot No. KK005-113	1	<2×10 ¹	<1.30	<3.05	<2.00×10 ¹	>99.9%
	2	6.8×10 ³	3.83			
	3	1.1×10 ³	3.04			
	4	9.8×10 ³	3.99			
	5	1.2×10 ³	3.08			

Test Organism: <i>Staphylococcus aureus</i> (ATCC 6538)						
Test Substance	Carrier #	CFU/Carrier	Log ₁₀	Avg. Log ₁₀	Geometric Mean	Reduction
Lot No. KK005-111	1	<2×10 ²	<2.30	<2.30	<2.00×10 ²	>99.9%
	2	<2×10 ²	<2.30			
	3	<2×10 ²	<2.30			
	4	<2×10 ²	<2.30			
	5	<2×10 ²	<2.30			
Lot No. KK005-112	1	<2×10 ²	<2.30	<2.30	<2.00×10 ²	>99.9%
	2	<2×10 ²	<2.30			
	3	<2×10 ²	<2.30			
	4	<2×10 ²	<2.30			
	5	<2×10 ²	<2.30			
Lot No. KK005-113	1	<2×10 ²	<2.30	<2.30	<2.00×10 ²	>99.9%
	2	<2×10 ²	<2.30			
	3	<2×10 ²	<2.30			
	4	<2×10 ²	<2.30			
	5	<2×10 ²	<2.30			

Carrier Control Population Results for Soft Surface Carriers		
Test Organism	Carrier Material	Geometric Mean (Avg. Log ₁₀)
<i>Enterobacter aerogenes</i>	100% Plain Cotton Weave	6.84
	100% Polyester	7.02
<i>Staphylococcus aureus</i>	100% Plain Cotton Weave	7.08
	100% Polyester	6.21

Hard Surface Fungistat Spray Results

MRID	Organism	Carrier No.	Percentage Growth Coverage at Day 7				
			Untreated Control	Lot KK005-111		Lot KK005-112	
				Visual	Magnified	Visual	Magnified
498987-32	<i>Aspergillus niger</i> (ATCC 6275)	1	60%	0%	No Growth	0%	No Growth
		2	75%	0%	No Growth	0%	No Growth
		3	70%	0%	No Growth	0%	No Growth
		4	70%	0%	No Growth	0%	No Growth
		5	65%	0%	No Growth	0%	No Growth
		6	80%	0%	No Growth	0%	No Growth
		7	80%	0%	No Growth	0%	No Growth
		8	65%	0%	No Growth	0%	No Growth
		9	65%	0%	No Growth	0%	No Growth
		10	75%	0%	No Growth	0%	No Growth

MRID 498987-33 Test Results for Phoenix 2, Lot KK005-111

Test Organisms: <i>Aspergillus niger</i> (ATCC 6275) and <i>Penicillium variable</i> (ATCC 32333)								
Carrier #	Evaluation of Test Carriers							
	Day 7		Day 14		Day 21		Day 28	
	Visual	Magnified	Visual	Magnified	Visual	Magnified	Visual	Magnified
1	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
2	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
3	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
4	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
5	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
6	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
7	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
8	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
9	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
10	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth

MRID 498987-33 Test Results for Phoenix 2, Lot KK005-112

Test Organisms: <i>Aspergillus niger</i> (ATCC 6275) and <i>Penicillium variable</i> (ATCC 32333)								
Carrier #	Evaluation of Test Carriers							
	Day 7		Day 14		Day 21		Day 28	
	Visual	Magnified	Visual	Magnified	Visual	Magnified	Visual	Magnified
1	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
2	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
3	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
4	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
5	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
6	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
7	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
8	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
9	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
10	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth

V CONCLUSIONS

1. The submitted efficacy data **support** the product as a ready-to-use disinfectant against the following organisms on hard, non-porous surfaces, for a 1-minute contact time at room temperature (20-21°C):

<i>Pseudomonas aeruginosa</i>	ATCC 15442	498987-13
<i>Staphylococcus aureus</i>	ATCC 6538	498987-13

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Control counts were acceptable.

2. The submitted efficacy data **do not support** the product as a ready-to-use disinfectant against the following organisms on hard, non-porous surfaces, for a 1-minute contact time at room temperature (20-21°C):

<i>Salmonella enterica</i>	ATCC 10708	498987-13
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Acceptable killing was not observed in the subcultures of the required number of carriers tested against the required number of product lots.

3. The submitted efficacy data **support** the product as a ready-to-use disinfectant against the following organisms on hard, non-porous surfaces, in the absence of an organic soil load, for a 1-minute contact time at room temperature (20-21°C):

<i>Enterobacter aerogenes</i>	ATCC 13048	498987-14
<i>Escherichia coli</i> O157:H7	ATCC 43888	498987-15
<i>Listeria monocytogenes</i>	ATCC 19117	498987-16
<i>Staphylococcus aureus</i> -MRSA	ATCC 33592	498987-17
<i>Streptococcus pyogenes</i>	ATCC 12384	498987-18

Acceptable results were observed in the required number of carriers tested against the required number of product lots. Neutralization confirmation testing was acceptable. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Control counts were acceptable.

4. The submitted efficacy data **support** the ready-to-use product as a disinfectant with fungicidal activity against the following fungi on hard, non-porous surfaces, with 5% organic soil load for a 5-minute contact time at room temperature (20-21°C):

<i>Trichophyton mentagrophytes</i>	ATCC 9533	498987-19
<i>Aspergillus niger</i>	ATCC 6275	498987-20

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Control counts were acceptable.

5. The submitted efficacy data **support** the ready-to-use product as a disinfectant with virucidal activity against the following viruses on hard non-porous surfaces with no organic soil load for a 60-second contact time at room temperature (20°C):

Human Coronavirus (ATCC VR-740, Strain 229E)	498987-21
Herpes simplex virus type 1 ATCC VR-733, Strain F(1)	498987-23
Herpes simplex virus type 2 (ATCC VR-734, Strain G)	498987-24
2009-H1N1 Influenza A virus	
Novel H1N1 Strain A/Mexico/4108/2009 CDC #2009712192	498987-25
Respiratory syncytial virus (ATCC VR-26, Strain Long)	498987-26

Recoverable virus titers of at least 10^4 were achieved. Complete inactivation (no growth) was observed in all dilutions tested in studies where no cytotoxicity was observed. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

6. The submitted efficacy data **support** the ready-to-use product as a disinfectant with virucidal activity against the following viruses on hard non-porous surfaces with 1% organic soil load for a 5-minute contact time at room temperature (20°C):

Feline Calicivirus (ATCC VR-782)	498987-22
Rhinovirus type 39 (ATCC VR-340, Strain 209),	498987-27

Recoverable virus titers of at least 10^4 were achieved. Complete inactivation (no growth) was observed in all dilutions tested in studies where no cytotoxicity was observed. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

7. The submitted efficacy data **support** the ready-to-use product as a disinfectant with virucidal activity against the following virus on hard non-porous surfaces with no organic soil load for a 5-minute contact time at room temperature (20°C):

Rotavirus (ATCC VR-2018, Strain WA)	498987-28
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Recoverable virus titers of at least 10^4 were achieved. Complete inactivation (no growth) was observed in all dilutions tested in studies where no cytotoxicity was observed. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

8. The submitted efficacy data **support** the ready-to-use product as a non-food contact surface sanitizer against the following bacteria on hard, non-porous, non-food contact surfaces for a 10-second contact time at room temperature (20°C):

<i>Enterobacter aerogenes</i>	ATCC 13048	498987-29
<i>Staphylococcus aureus</i>	ATCC 6538	498987-29

9. The submitted efficacy data **support** the ready-to-use product as a residual self-sanitizing surface sanitizer against the following bacteria on hard, non-porous, non-food contact surfaces at room temperature (20°C):

<i>Enterobacter aerogenes</i>	ATCC 13048	498987-30
<i>Staphylococcus aureus</i>	ATCC 6538	498987-30

10. The submitted efficacy data **support** the ready-to-use product as a non-food contact surface sanitizer against the following bacteria on soft surfaces at room temperature (20°C):

<i>Enterobacter aerogenes</i>	ATCC 13048	498987-31
<i>Staphylococcus aureus</i>	ATCC 6538	498987-31

11. The submitted efficacy data **support** the ready-to-use product as a disinfectant with fungicidal activity as a hard surface fungistat at room temperature (20-21°C):

<i>Aspergillus niger</i>	ATCC 6275	498987-32
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Treated carriers showed no growth of test organism through seven days incubation while control carriers showed acceptable growth of test organism. Sterility controls did not show growth.

12. The submitted efficacy data **support** the ready-to-use product as a disinfectant with fungicidal activity as a soft surface fungistat at room temperature (20-21°C):

<i>Aspergillus niger</i>	ATCC 6275	498987-32
<i>Penicillium variable</i>	ATCC 32333	498987-32

Treated carriers showed no growth of test organism through 7 day intervals over 28 days incubation while control carriers showed acceptable growth of test organism. Sterility controls did not show growth.

V RECOMMENDATIONS

1. The label claims that the product is a ready-to-use disinfectant against the following organisms on hard, non-porous surfaces, for a 1-minute contact time:

<i>Pseudomonas aeruginosa</i>	ATCC 15442
<i>Staphylococcus aureus</i>	ATCC 6538

These claims are acceptable as they are supported by the submitted efficacy data.

2. The label claims that the product is a ready-to-use disinfectant against the following organisms on hard, non-porous surfaces, for a 1-minute contact time:

<i>Salmonella enterica</i>	ATCC 10708
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These claims are **not acceptable** as they are not supported by the submitted efficacy data.

3. The label claims that the product is a disinfectant against the following organisms on hard, non-porous surfaces for a 1-minute contact time:

<i>Enterobacter aerogenes</i>	ATCC 13048
<i>Escherichia coli</i> O157:H7	ATCC 43888
<i>Listeria monocytogenes</i>	ATCC 19117
<i>Staphylococcus aureus</i> -MRSA	ATCC 33592

Streptococcus pyogenes

ATCC 12384

These claims are acceptable as they are supported by the submitted efficacy data.

4. The label claims that the product is a disinfectant with fungicidal activity against the following fungi on hard, non-porous surfaces, for a 5-minute contact time:

Trichophyton mentagrophytes
Aspergillus niger

ATCC 9533
ATCC 6275

These claims are acceptable as they are supported by the submitted data.

5. The label claims that the product is a disinfectant with virucidal activity against the following viruses with a 1 minuter contact time on hard non-porous surfaces:

Human Coronavirus
Herpes simplex virus type 1
Herpes simplex virus type 2
2009-H1N1 Influenza A virus

ATCC VR-740, Strain 229E
ATCC VR-733, Strain F(1)
ATCC VR-734, Strain G)

Novel H1N1 Strain A/Mexico/4108/2009 CDC #2009712192
Respiratory syncytial virus

ATCC VR-26, Strain Long

These claims are acceptable as they are supported by the submitted data.

6. The label claims that the product is a disinfectant with virucidal activity against the following viruses for a 5 minute contact time on hard non-porous surfaces:

Feline Calicivirus
Rhinovirus type 39

ATCC VR-782)
ATCC VR-340, Strain 209

These claims are acceptable as they are supported by the submitted data.

7. The label claims that the product is a disinfectant with virucidal activity against the following viruse on hard non-porous surfaces with no organic soil load for a 5 minute contact time:

Rotavirus

ATCC VR-2018, Strain WA

These claims are acceptable as they are supported by the submitted data.

8. The label claims that the product is a non-food contact surface sanitizer against the following bacteria on hard, non-porous, non-food contact surfaces for a 10-second contact time:

Enterobacter aerogenes
Staphylococcus aureus

ATCC 13048
ATCC 6538

These claims are acceptable as they are supported by the submitted data.

9. The label claims that the product is a residual self-sanitizing surface sanitizer against the following bacteria for a 5 minute contact time on hard, non-porous, non-food contact surfaces:

Enterobacter aerogenes
Staphylococcus aureus

ATCC 13048
ATCC 6538

These claims are acceptable as they are supported by the submitted data.

10. The label claims that the product is a non-food contact surface spot sanitizer with a 5 minute contact time against the following bacteria on soft surfaces:

Enterobacter aerogenes
Staphylococcus aureus

ATCC 13048
ATCC 6538

These claims are acceptable as they are supported by the submitted data.

11. The label claims that the product is a disinfectant with fungicidal activity against mold and mildew (*Aspergillus niger*, ATCC 6275) on hard, non-porous surfaces for a 7 day duration. These claims are acceptable as they are supported by the submitted data.
12. The label claims that the product is a disinfectant with fungicidal activity against mold and mildew on soft surfaces (*Aspergillus niger* ATCC 6275 and *Penicillium variable* ATCC 32333) for a 28 day duration. This claims is acceptable as it is supported by the submitted data.

VI LABEL COMMENTS (version 042716):

- Page 1; directly under "Phoenix 2," [Sanitizer], change to [non-food contact surface sanitizer]
- Page 2; {Sanitizing Directions}, include, "Thoroughly clean surface to be treated prior to sanitization." Remove, "Pre-clean heavily soiled surfaces."
- Page 3; remove [(black mold)]
- Page 6; remove all instances of [One Step] [1 Step] through the label as well as similar instances such as, "...in one quick fast rapid step."
- Page 6; Label claims can only say sanitizes for 24 hours or kills 99.9% of bacteria for 24 hours.
 - Page 6; "Kills 99.9% of bacteria ... for 24 hours," include, "on treated surfaces."
 - Page 6; Remove "Prevents [bacterial growth]"
 - Page 6; Remove "24 hour continuous bacteria protection"
 - Page 6; Remove "[The cleaner that] provides continuous sanitization"
 - Page 6; Remove "Protects from what you can't see 24 hours of protection"
 - Page 6; Remove "24 hour protection"
- Page 6; Remove "[Only]" in reference to Microban continues to kill...
- Page 6; Remove "Nothing kills bacteria longer than Microban"
- Page 6; Remove "Protects household surfaces ... for up to 24 hours"
- Page 6; Remove "Provides 24 hour continuous ... protection"
- Page 6; Remove "Provides 24 hour antimicrobial disinfection against bacteria"
- Page 7; Remove "Provides enduring protection"
- Page 7; Remove "Leaves behind a ... for 24 hours"
- Page 7; Remove "Bacteria fighting protection for 24 hours"
- Page 7; Remove instances of "[24 hour protection]"
- Page 7-8; Disinfecting Claims – remove all instances of "[free from germs]," [germ-free home],
- Page 7-8; Disinfecting Claims – remove all instances of "mold" and/or "mildew."
- Page 7; Disinfecting Claims – remove [in one step]

- Page 8; Disinfecting Claims – Change [on hard nonporous surfaces] to [on treated hard nonporous surfaces].”
- Page 8; “Helps fight the spread of germs ... [on hard nonporous surfaces],” change to, “[on treated hard nonporous surfaces]”
- Page 8; Change {Soft Surface Sanitizer} to {Soft Surface Spot Sanitizer}